July 6, 2022

S&C Polymer Silicon- und Composite Spezialitäten GmbH
Christian Böttcher
Reg. Compliance Officer, Official Correspondent to FDA
Robert-Bosch-Str. 2
Elmshorn, 25335
Germany

Re: K221033
Trade/Device Name: UniPrime A, UniPrime E, UniPrime E/C
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: March 31, 2022
Received: April 7, 2022

Dear Christian Böttcher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221033

Device Name
UniPrime A
UniPrime E
UniPrime E/C

Indications for Use *(Describe)*

UniPrime A

UniPrime A is a MDP containing universal primer 1) for the bonding of methacrylate based dental materials to zirconia and metal/alloy frameworks, crowns and bridges and 2) for the intraoral repair of fractured restorations made of zirconia and metal/alloy.

UniPrime E

UniPrime E is a MDP containing universal primer 1) for the bonding of methacrylate based dental materials to zirconia, composite and metal/alloy frameworks, crowns and bridges and 2) for the intraoral repair of fractured restorations made of zirconia, composite and metal/alloy.

UniPrime E/C

UniPrime E/C is a MDP containing universal primer 1) for the bonding of methacrylate based dental materials to ceramic, zirconia, composite and metal/alloy frameworks, crowns and bridges and 2) for the intraoral repair of fractured restorations made of ceramic, zirconia, composite and metal/alloy.

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary - K221033

1. Submitter

Name of company:	S&C Polymer Silicon- und Composite Spezialitäten GmbH
Address:	Robert-Bosch-Str. 2, 25335 Elmshorn, Germany
Phone:	0049 4121 483 0
Fax:	0049 4121 483 184
Contact person:	Dr. Christian Böttcher
Date prepared:	March 31st 2022

2. Device name

Trade name:	UniPrime A UniPrime E UniPrime E/C
Common name:	Universal primer
Device classification name:	Agent, tooth bonding resin
Regulatory number:	872.3200
Product code:	KLE

3. Device description

UniPrime A is a MDP containing universal primer for the bonding of methacrylate based dental materials to zirconia and metal/alloy frameworks, crowns and bridges (indications from labeling).

UniPrime E is a MDP containing universal primer for the bonding of methacrylate based dental materials to zirconia, composite and metal/alloy frameworks, crowns and bridges (indications from labeling).

UniPrime E/C is a MDP containing universal primer for the bonding of methacrylate based dental materials to ceramic, zirconia, composite and metal/alloy frameworks, crowns and bridges (indications from labeling).

4. Intended use of the devices

UniPrime A improves the bonding of methacrylate based dental materials to zirconia and metal/alloy frameworks, crowns and bridges.

UniPrime E improves the bonding of methacrylate based dental materials to zirconia, composite and metal/alloy frameworks, crowns and bridges.

UniPrime E/C improves the bonding of methacrylate based dental materials to ceramic, zirconia, composite and metal/alloy frameworks, crowns and bridges.

5. Indication for use of the devices

UniPrime A is a MDP containing universal primer 1) for the bonding of methacrylate based dental materials to zirconia and metal/alloy frameworks, crowns and bridges and 2) for the intraoral repair of fractured restorations made of zirconia and metal/alloy.

UniPrime E is a MDP containing universal primer 1) for the bonding of methacrylate based dental materials to zirconia, composite and metal/alloy frameworks, crowns and bridges and 2) for the intraoral repair of fractured restorations made of zirconia, composite and metal/alloy.

UniPrime E/C is a MDP containing universal primer 1) for the bonding of methacrylate based dental materials to ceramic, zirconia, composite and metal/alloy frameworks, crowns and bridges and 2) for the intraoral repair of fractured restorations made of ceramic, zirconia, composite and metal/alloy.

6. Device for which substantial equivalence is claimed

Subject device:	UniPrime A UniPrime E UniPrime E/C
Predicate device:	Clearfil Ceramic Primer Plus (Kuraray)
510(k) Number:	K150703 (introduced into the US-Market 2015)

6.1. Device comparison with the predicate device

The predicate device has been found to be substantially equivalent under the 510(k) premarket notification as class II dental device under CFR 872.3200 product code KLE.

	Subject devices UniPrime A UniPrime E UniPrime E/C	**Predicate device Clearfil Ceramic Primer Plus (Kuraray)**
Device description	MDP containing universal primer for the bonding of methacrylate based dental materials to ceramic, zirconia, composite and metal/alloy frameworks, crowns and bridges.*	Clearfil Ceramic Primer Plus
Intended use	UniPrime improves the bonding of methacrylate based dental materials to ceramic, zirconia, composite and metal/alloy frameworks, crowns and bridges.*	Clearfil Ceramic Primer Plus is a dental universal prosthetic primer that provides an enhanced adhesive surface to ceramic, hybrid ceramics, composite resin and metal.
Prescription use	yes	yes

Mechanism of action	equal	equal
Form of delivery	bottle	bottle
Indications for use	UniPrime II improves the bonding of methacrylate based dental materials to ceramic, zirconia and metal/alloy frameworks, crowns and bridges.*	Clearfil Ceramic Primer Plus is indicated for the following uses: -Surface treatment of prosthetic restorations made of ceramic, hybrid ceramics, composite resin or metal Intraoral repairs of fractured Restorations made of ceramic hybrid ceramics, composite resin or metal
Ingredients	Solvent MDP Silane *	Solvent MDP Silane

* product specific information

7. Conclusion

The comparison worked out above and the further elaboration of information within this 510(k) submission demonstrate that the subject devices UniPrime A, UniPrime E and UniPrime E/C are substantially equivalent to the predicate device Clearfil Ceramic Primer Plus (Kuraray) in terms of description, intended use, indications for use, chemical composition and physical properties. The subject device has been evaluated for adhesive strength to indicated surfaces, pH, and biocompatiblity. The information given above do not raise different questions of safety and effectiveness. The devices are as safe and effective as the predicate device.